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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,558	10/20/2000	Elfi Biedermann	25846-0003	7777

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EXAMINER	
ANDERSON, JAMES D	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/693,558	BIEDERMANN ET AL.	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 25 October 2006.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 57-82 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 57-82 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Change of Examiner

The examiner of the instant application has changed. The new examiner is James D. Anderson, Ph.D. Contact information is provided at the end of this Office Action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 57-71, drawn to a pharmaceutical composition comprising a compound of Formula (I) and a compound having vitamin PP activity, selected from compounds of Formula II, IIa, IIb, III, IIIa, IIIb, IIIc, IV, IVa, IVb, V, Va and Vb, classified in class 514, subclass 315. **NOTE: Additional Election of Species requirement is outlined below if this group is elected.**

II. Claims 72-81, drawn to a method of reducing side effects or neutralizing the side effects of a cancerostatic or immunosuppresive agent comprising administering a compound having vitamin PP activity, classified in class 514, subclass 315. **NOTE: Additional Election of Species requirement is outlined below if this group is elected.**

III. Claim 82, drawn to a method according to claim 73 wherein a further cancerostatic or immunosuppresive agent, different from compounds of Formula I is administered, classified in class 514, subclass 315. **NOTE: Additional Election of Species requirement is outlined below if this group is elected.**

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II/III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the methods of use recited in the claims of Groups II-III do not require the specific composition recited in the claims of Group I. For example, the composition of Group I comprises a cancerostatic or immunosuppresive agent of Formula (I) and a compound having vitamin PP activity selected from compounds of Formula II, IIa, IIb, III, IIIa, IIIb, IIIc, IV, IVa, IVb, V, Va and Vb. However, the method according to the claims of Group II does not require that the cancerostatic or immunosuppresive agent be of Formula (I) or the compound having vitamin PP activity be selected from compounds of Formula II, IIa, IIb, III, IIIa, IIIb, IIIc, IV, IVa, IVb, V, Va and Vb (*e.g.* Claim 72). Further, claim 78 of Group II does not require the specific cancerostatic or immunosuppressive agent recited in the composition of Group I. It is noted that the compounds of Formula I recited in claim 78 are similar to those recited in the claims of Group I. However, the specific substituents are different. As such, the compounds of Formula I recited in claim 57 of Group I are not the same as those recited in claim 78 of Group II. Thus, the process for using the product (composition) claimed in Group I can be practiced with a materially different product (*i.e.* a cancerostatic or immunosuppressive agent NOT of Formula I and/or compounds having vitamin PP activity NOT of Formulas II, IIa, IIb, III, IIIa, IIIb, IIIc, IV, IVa, IVb, V, Va or Vb). With respect to Group III, claim 82 requires the administration of a cancerostatic or immunosuppresive agent NOT of Formula I. Thus,

administration of a composition according to the claims of Group I does not meet the limitation required in the method of Group III. As such, the invention of Group I is patentably distinct from the inventions of Groups II-III.

Inventions II and III are directed to related methods of reducing side effects or neutralizing the side effects of a cancerostatic or immunosuppresive agent comprising the administration of a compound having vitamin PP activity. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed do not overlap in scope and are not capable of use together. Claim 82 of Group III requires the administration of a cancerostatic or immunosuppresive agent NOT of Formula I. Thus, practicing the method as recited in the claims of Group II will not meet the limitation required in the method of Group III. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species Requirement

Claims 57-82 are generic to the following disclosed patentably distinct species: 1) compounds having vitamin PP activity (*e.g.* compounds of Formula II, IIa, IIb, III, IIIa, IIIb, IIIc, IV, IVa, IVb, V, Va or Vb), and 2) compounds of instant Formula I, as disclosed throughout the subject specification and claims. The various compounds of instant formula I where the E or G terms may be heterocyclic moieties are repugnant to accepted principles of scientific classification. A plethora of compounds are encompassed within the definitions of E and G. The search required for a method and/or composition where G is dihydrobenzothienothiepinyl, for example, would vary from a method and/or composition where G is tetrahydroisoquinolinyl. Distinctness of the methods/compositions is evidenced by the different classification based on the many heterocycles disclosed in the specification and claims for E and G. As such, depending on the selection of groups for E and G, compounds of instant formula I will no longer share a substantial common structural feature that is essential to activity. As to the burden of the search, classification is merely one indication of the burdensome nature of the required search. The literature search of the large number of possible compounds of instant Formula I claimed herein is not necessarily co-extensive and is a major factor in determining search burden.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species of compound having vitamin PP activity and a single disclosed species of Formula I, even though this requirement is traversed. Should Applicants traverse on the ground that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the

evidence or admission may be used in a rejection under 35 U.S.C. § 103 (a) of the other invention.

Applicants are advised that to be complete, the reply to this requirement must include an election of the invention to be examined even though the requirement is traversed (37 CFR § 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(I).

Notice of Possible Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR § 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C.

§§ 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James D. Anderson, Ph.D.
Patent Examiner
AU 1614

December 29, 2006

Phyllis Spivack
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PRIMARY EXAMINER
12/31/06

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